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10/796,103	03/10/2004	Hiroshi Takiguchi	119037	2367

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EXAMINER	
STEELE, AMBER D	
ART UNIT	**PAPER NUMBER**
1639	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,103	TAKIGUCHI ET AL.	
	Examiner	Art Unit	
	Amber D. Steele	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/9/2007; 11/27/2006; and 8/22/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *10 and 19-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/27/04; 3/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. The preliminary amendment received on March 10, 2004 amended claim 19.

Claims 1-25 are currently pending.

Claims 1-9 and 11-18 are currently under consideration.

Election/Restrictions

2. Applicant's election with traverse of Group I (present claims 1-18) in the reply filed on August 22, 2006 is acknowledged. The traversal is on the ground(s) that a serious search burden does not exist. This is not found persuasive because the restriction requirement mailed on July 28, 2006 shows that a serious search burden exists due to the different class and/or subclass for each group. In addition, a serious search burden exists because a search of a method of making an array (i.e. method of immobilizing nucleic acid on a solid phase substrate) would not necessarily encompass a search of biosensors or a method of detecting target nucleic acids in a test sample. Specifically, their are references directed to biosensors that do not describe production of nucleic acid arrays, references directed to producing nucleic acid arrays may not describe utilizing the array in a nucleic acid screening method, references directed to producing nucleic acid arrays may screen for proteins which bind to the array (e.g. not nucleic acids that bind), etc.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 19-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on August 22, 2006.

4. Applicant's election with traverse of a probe according to claim 3 wherein L3 is a C6 alkylene group and L4 is a polyethylene glycol phosphate group as the species of probe; a compound according to formula (I) wherein L1 is a C6 alkylene group, L2 is a single bond, and R is a hydroxyl group as the species of compound; and HS are hydrogen and sulfur, respectively in the replies filed on November 27, 2006 and March 9, 2007 is acknowledged. The traversal is on the ground(s) that a serious search burden does not exist. This is not found persuasive because the various structures and/or formulas are different.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the replies filed on November 27, 2006 and March 9, 2007.

Priority

6. The present application claims foreign priority to JP 2003-086362 filed March 26, 2003.

7. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. However, a translation of JP 2003-086362 has not been provided.

Information Disclosure Statement

8. The information disclosure statements (IDS) submitted on August 27,2004 and March 10, 2004 are being considered by the examiner. Please note: a date for the Takiguchi et al. reference has not been provided.

Invention as Claimed

9. A method for immobilizing nucleic acid on a solid phase substrate comprising: (a) bringing the solid phase substrate into contact with a composition comprising a total concentration of 0.1 to 2 μM of a nucleic acid as a probe and a compound or a salt thereof wherein the compound has a formula represented by HS-L^1-L^2-R wherein L^1 is a single bond or a C_{1-15} alkylene group; L^2 is a single bond, a nucleic acid, a polyethylene glycol group, -CO-NH-, or –NH-CO-; and R is a hydroxyl group, an amino acid group, a ferrocenyl group, or a carboxyl group provided that neither L^1 nor L^2 is a single bond and (b) incubating the composition in contact with a surface of the solid phase substrate and variations thereof.

Please note: claims 15 and 18 recite "may" further comprise and "may" also, therefore, the limitations are considered optional.

Claim Objections

10. Claims 1-9 and 11-18 are objected to because of the following informalities: the claims comprise various Markush groups but are not in proper Markush format (i.e. selected from the group consisting of A, B, and C). For example: claim 1 recites L^1 is a single bond or a C_{1-15} alkylene group wherein the second alternative (i.e. C_{1-15} alkylene group) comprises multiple species. Please refer to MPEP § 2173.05(h). Appropriate correction is required.

11. Claim 2 is objected to because of the following informalities: while the full names of the acronyms CNA and HNA are provided on page 11 (e.g. cyclohexanyl nucleic acid and hexitol nucleic acid, respectively) of the present specification, the acronyms CNA and HNA have various definitions in the art (e.g. CNA = cyclohexanyl/cyclohexane nucleic acid, constrained nucleic acid, carbamate linked nucleic acid, circulating nucleic acid, containing nucleic acid, etc. and HNA = hexitol nucleic acid, high nucleic acid, hairpin nucleic acid, header nucleic acid, etc.). Thus, applicants are requested to insert the full name into the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites "nucleic acid as a probe comprises a polynucleotide or an oligonucleotide consisting of modified or unmodified...". One of skill in the art would not be able to determine the scope of the presently claimed invention. For example, can modified polynucleotides or oligonucleotides comprise the addition of tags, linkers, amino acids, inorganic molecules, inorganic molecules, etc. or can "unmodified" polynucleotides or oligonucleotides comprise "wildtype" nucleic acids, naturally occurring mutations, etc.? The specification only "defines" modified as "including substitutions" (please refer to page 11). Therefore, do "modified" polynucleotides or oligonucleotides comprise polynucleotides or oligonucleotides mutations, "substituting" uracil with thymidine, methylation, etc.?

14. Claims 1-9 and 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. Independent claim 1 recites "R is a hydroxyl group, an amino group, a ferrocenyl group, or a carboxyl group provided that neither L^1 nor L^2 is a single bond". However, an alternative for R if L^1 or L^2 is a single bond is not provided. For example, if L^1 or L^2 is a single bond then is R optional, not present, another molecule, etc.?

15. Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3 and 4 recite the limitation "spacer". One of skill in the art would not be able to determine the scope of the presently claimed invention. Claims 3 and 4 recite the limitation "spacer". For example, is a spacer a nucleic acid, an amino acid, an inorganic molecule, etc.? The specification only "defines" spacer as "low molecular weight molecules" or "low molecular weight substances" (please refer to pages 2 and 12).

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

> international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 1-9 and 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al. The effect of surface probe density on DNA hybridization Nucleic Acids Research 29(24): 5163-5168, 2001.

For present claims 1, 6-9, 11-12, and 18, Peterson et al. teach methods for immobilizing nucleic acids on a solid phase substrate comprising (a) contacting a nucleic acid probe and a duplex (i.e. compound) of formula HSC_6-nulceic acid (e.g. HS-L^1-L^2-R wherein L^1 is C_6, L^2 is a single bond, and R is natural hydroxyl on 3' end of nucleic acid) with a solid support and (b) incubating the probe, compound, and solid support wherein the concentration of the probe, target, and duplex solutions are 1 μM (please refer to entire document particularly Table 1 and Materials and Methods section). In addition, Peterson et al. teach mercaptohexanol (please refer to entire document particularly Materials and Methods section). Please note: the Office does not have the facilities and resources to provide the factual evidence needed in order to determine the ratio of the probe and duplex provided by Peterson et al. correlate to the 60/40 or 40/60 ratio as presently claimed in claim 8. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the ration is different from the ones taught by the prior art and to establish the patentable differences. See in re Best 562F.2d 1252, 195 U. S. P. Q. 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

For present claim 2, Peterson et al. teach ssDNA as the nucleic acid probe (please refer to entire document particularly Table 1).

For present claims 3-4, Peterson et al. teach 5' end of the nucleic acid probe as formula of HSC_6single bond or HSC_6spacer (e.g. HS-L3-L4 wherein L3 is C6 and L4 is a single bond or spacer; please refer to entire document particularly Table 1).

For present claim 5, Peterson et al. teach probe with nucleic acid (e.g. spacer; please refer to entire document particularly Table 1).

For present claims 13-15, Peterson et al. teach gold SPR substrate (e.g. gold on glass; please refer to entire document particularly Materials and Methods section).

For present claim 16, Peterson et al. teach probes 25 base pairs in length (please refer to entire document particularly Table 1).

For present claim 17, Peterson et al. teach incubation at room temperature (e.g. 25°C; please refer to entire document particularly Materials and Methods).

Therefore, the presently claimed invention is anticipated by the teachings of Peterson et al.

18. Claims 1-9, 11-13, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Bawendi et al. U.S. Patent 6,855,551 filed April 12, 2001 (effective filing date September 18, 1998).

For present claims 1, 3-4, 6-9, 11-12, Bawendi et al. teach methods of making semiconductor nanocrystals/quantum dots comprising (a) bringing a quantum dot (e.g. solid phase substrate) into contact with nucleic acid probes including HS-alkylene-PEG wherein alkylene is C_6 and a HS-alkylene-hydroxyl compound wherein the alkylene includes C_6 and (b) incubating the solid phase and the nucleic acid and HS-alkylene-hydroxyl compound (please

refer to the entire specification particularly abstract; Figures 3-4, 6, 8-9; columns 4-14; Examples 1-10). Please note: the Office does not have the facilities and resources to provide the factual evidence needed in order to determine the concentration of the nucleic acids and compounds taught by Bawendi et al. or the ratio of the nucleic acids and compounds taught by Bawendi et al. correlate to the 60/40 or 40/60 ratio as presently claimed in claim 8. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the ration is different from the ones taught by the prior art and to establish the patentable differences. See in re Best 562F.2d 1252, 195 U. S. P. Q. 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

For present claim 2, Bawendi et al. teach DNA and RNA (please refer to the entire specification particularly columns 4, 6-7, 9-14).

For present claim 5, Bawendi et al. teach polyethylene glycol (please refer to the entire specification particularly column 8).

For present claim 13, Bawendi et al. teach quantum dots made of metal (please refer to the entire specification particularly column 5; Examples 1-2).

For present claim 17, Bawendi et al. teach room temperature (e.g. 25°C; please refer to the entire specification particularly Examples 9-10).

Therefore, the presently claimed invention is anticipated by the teachings of Bawendi et al.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JON EPPERSON
PRIMARY EXAMINER

ADS
May 18, 2007